

REMARKS

This Amendment is responsive to the Office Action mailed October 27, 2006. Claims 11, 16 and 20 are amended herein. Claims 16 and 20 have been amended merely to place the claims in a more traditional U.S. format. Claims 12-13 are canceled. Thus, claims 11 and 14-21 remain pending. Reconsideration is respectfully requested.

The present invention discloses binary, single phase titanium-zirconium alloys having a zirconium content of more 10% to less 19% by weight, 0.1% to 0.3% by weight oxygen and not more than 1% by weight of additional strength enhancing additives and technical impurities. Said alloys are further characterized in that they are obtainable by hot forging above a/b phase transition and rapid cooling and subsequent cold processing of said alloy.

The tensile strength is important for implants having a small diameter (3.3mm or less). Implants made of pure Ti are not optimal since they tend to break. Implants made of pure Zr also cannot be employed.

However, it has been discovered that tensile strength is only one of several important criteria which are critical when TiZr-alloys are used for the production of surgical implants. While tensile strength increases with an increasing Zr-content up to 50% Zr and subsequently decreases again, it has been discovered that a maximized tensile strength is disadvantageous for surgical implants, particularly when used in the dental field. Stress at break is a measure of the toughness of a metal (specification page 8, first paragraph).

Applicants recognized that TiZr-alloys having an elongation at break between 18.1% and 10.9% and a stress at break in the range of 1436 MPa and 1454 MPa have a much lower risk of failure. At a Zr-content of 25.6% by weight the elongation at break drops below 10% (page 6, table 1 of the specification). An elongation at break below 10% renders TiZr-alloys highly disadvantageous for the production of surgical implants. Thus, elongation at break and stress at break are additional result-effective parameters.

Cell cultures are a suitable test for measuring the reactions in the presence of metallic foreign bodies. In hard tissue experiments with osteoblast cells are of interest, it has been shown that TiZr-alloys according to the present invention do not cause any retardation in the growth of cultured osteoblasts (specification page 9, table 5).

To achieve an excellent osteo-integration the implant surface is treated prior to implantation, e.g. by sandblasting and subsequent acid etching. This treatment yields a surface comprising a macro-roughness and an imposed micro-roughness.

It was found that the above-mentioned treatment cannot be applied to any TiZr-alloy. For instance, if alloys comprising a and b phases are subjected to an acid etching, the desired surface having a macro-and micro-roughness cannot be achieved. The reason for this is the different susceptibility of the two phases to the acid treatment. Rather, a patch-like surface with areas of different roughness is obtained. The different effects of sandblasting and acid etching on a pure a-phase alloy (Figure 1: Ti13Zr) and on a a/b phase alloy (Figure 2: Ti6Al7Nb) are illustrated by the enclosed pictures. In figure 2 grains comprising b-phase niobium are clearly visible.

The macro- and micro-roughness, however, are crucial elements for an excellent osteo-integration. Thus, certain treatments of the surface require a single phase alloy. Bearing this in mind a skilled person would be highly disinclined to employ dual phase titanium-zirconium alloys irrespective of the fact that such alloys may have the desired strength rendering them suitable implants. In contrast, binary single phase TiZr-alloys according to the present invention possess a surface which is suitable for the above-mentioned treatment.

The unique combination of a high strength of TiZr-alloys according to the present invention and their suitability of subsequent surface treatment resulting in a roughened surface cannot be achieved with standard materials such as pure titanium.

Claims 11, 13-15, 17-19 and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over GB1,305,879 ('879).

'879 describes TiZr-Implants. The main components of the alloy are zirconium (Zr), the content of which is in the range of 25% to 75% weight, and titanium making up the remainder together with at most 3% of other elements.

Since an implant should have a suitable strength in order to reduce breaks to a minimum, not all TiZr alloys described show the necessary strength making them suitable as implant materials. This strength should typically be in the range of 780 to 880 MPa. Thus, a skilled person would use alloys having a Zr content which is higher than 35% by weight to ensure a strength sufficiently high for implants.

'879 teaches that the tensile strength of TiZr-alloys increases with an increasing Zr-content up to a Zr-content of 50% by weight. Tensile strength then decreases again. Thus one skilled in the art would choose TiZr-alloy having 50% by weight Zr in order to maximize the tensile strength. Such an alloy is consequently described to be the most preferred embodiment ('879, page 2, lines 31-38).

The Zr content of alloys according to the present invention as amended is in the range of more than 10% to less than 19% by weight which is substantially different from the Zr content taught by '879. In addition, rapid cooling is not mentioned. '879 only teaches tensile strength as result-effective parameter. It does not mention, let alone describe, the combination of the parameters tensile strength and elongation at break/stress at break. Thus, it would not be obvious to one skilled in the art to utilize a zirconium content of between 10-19 weight % for a surgical implant.

The examiner refers to Table 2 of '879 and states that the strength minimum is expected to result from a Ti 25% Zr alloy. The claims as amended include a maximum of Ti 19%.

The '879 patent actually teaches away from using zirconium in an amount less than 19 weight % because one skilled in the art reading Table 2 of '879 would believe that an alloy having such a low weight % of zirconium would not have the adequate tensile strength necessary for an implant. One skilled in the art reading '879 would use at least Ti35Zr and move preferably Ti50Zr. A prior art reference must be considered in its entirety, including those portions that would lead away from the claimed invention. MPEP § 2141.02.

Claims 11 and 13-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over '879 in view of Chemical Abstract 119: 103239 ('239) and U.S. 5,169,597 ('597).

'239 discloses alloys for implants containing titanium and 5 to 20 mass% Zr. Further elements of the alloy are Sn, Nb, Ta and Pd. The alloys described are binary TiZr-alloys having two phases (a and b phase). Nb and Ta are known to stabilize the b-phase. Therefore, a skilled person would expect to end up with a dual phase alloy.

However, as explained above, dual phase alloys are disadvantageous because their structure is not homogeneous thus making it difficult to achieve a desired surface topography in subsequent processing. Looking for suitable single phase titanium alloys and having the aforementioned in mind, a skilled person would consider '239 as a document leading him away from the claimed alloy.

In addition, the components Sn, Nb, and Ta described in '239 have been shown to cause retardation in the growth of cultured osteoblasts (see page specification of the present invention page 9, table 5). '239 indicates forging of the described TiZr-alloys in their alpha and alpha/beta region. However, since the alloys described in '239 contain significant amounts of further components (10-20% Sn, 4-8% Nb and 2-4% Ta), it is uncertain if the conditions indicated also apply to TiZr-alloys according to the present invention, which have no further components apart from oxygen and technical impurities, the amount of which is 1% by weight or less. There is also no indication in '239 that the conditions can be successfully applied to TiZr-alloys according to the present invention.

Thus, one skilled in the art would not be motivated to combine the teachings of '879 and '239. The mere fact references can be combined or modified does not render the result and combination obvious unless the prior art also suggest the desirability of the combination MPEP § 2143.01 III.

'597 discloses biocompatible titanium alloys containing titanium, niobium and up to 20% by weight zirconium. Ternary alloys never have a single phase. The alloys described in '597 inevitably have the disadvantages of a surface with an undesirable non-homogeneous structure preventing a good stabilization of an implant in its environment (e.g. bone). To reduce this disadvantage '597 suggests to the implant surface by sintering ('597, column 7, lines 9 to 16). Further, Nb has been demonstrated to cause retardation in the growth of osteoblast cells which is disadvantageous for osteointegration (see page specification of the present invention page 9, table 5).

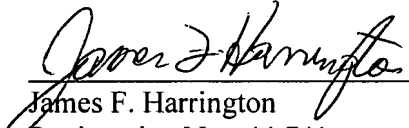
The Examiner states that '597 teaches rapid cooling after hot working of Ti-alloys thereby achieving a finer grain size and an adequate strength. However, '597 describes ternary, dual phase alloys and fails to show that the conditions disclosed are also applicable to binary, single phase TiZr-alloys and fails to show that the conditions disclosed are also applicable to binary, single phase TiZr-alloys according to the present invention. '597 provides no reasonable expectation of success to do so. Therefore, a skilled person would not reasonably consider using the teachings of '597 and would have no motivation to combine the teachings of '879 and '597.

Thus, the cited references do not render the subject matter of amended claim 11 obvious, either alone or in combination. The same applies to the dependant claims.

Applicant: Samuel Steinemann
Serial No.: 10/750,446
Filing Date: December 31, 2003
Docket No.: 1409-2 RCE/CON/RCE
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Accordingly, Applicant respectfully submits that the application is now in proper form for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to allowance of the application, it is respectfully requested that the Examiner contact Applicant's attorney at the telephone provided below.

Respectfully submitted,


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